McKesson Internal Audit

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Empowering Healthcare

Audit Report

Controlled Substance Monitoring Program

US Pharmaceutical

To: Krista Peck, Assistant General Counsel

From: Internal Audit Department

Subject: Controlled Substance Monitoring Program

	Current Audit	Prior Audit
Date Audit Completed:	November 2, 2012	August 25, 2008
Audit Report Date:	January 24, 2013	October 8, 2008
Report Reference Number:	13-SSPH-04	09-SSPH-04
Rating:	Green – Satisfactory	Yellow – Needs Improvement
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Mark Fuller
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P-00116_00001

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Executive Summary

Background

The US Pharmaceutical (US Pharma) FY12 revenues were $97.5 billion, which represents 79% of McKesson's total revenue and 83% of EBIT. US Pharma services over 40,000 customers spanning retail national accounts, independent retail pharmacies, and institutional providers (such as hospitals, health systems, integrated delivery networks, and long-term care providers). The distribution network is comprised of 31 (28 forward, 2 regional, 1 strategic) distribution centers (DCs) located in 30 states divided into four regions.

Controlled substances are defined as drug or other substance, or immediate precursor, included in DEA schedule I, II, II, IV, and V. The schedules are assigned by the DEA based on the potential for abuse and medical use. US Pharma distributes controlled substances for both US Pharma and the McKesson Medical-Surgical (MMS) business unit. In FY12 US Pharma distributed approximately 5.1 million lines of controlled substance orders resulting in $1.1 billion in sales, and MMS distributed 3,300 lines resulting in $637,000 in sales.

US Pharma enhanced its Controlled Substance Monitoring Program (CSMP) in connection with the U.S. Drug Enforcement Administration (DEA) agreement entered into on May 2, 2008. This agreement requires McKesson to establish a compliance program designed to detect and prevent the diversion of controlled substances as stipulated under the Controlled Substances Act and applicable DEA regulations. The CSMP includes policies and procedures, automated controls and Directors of Regulatory Affairs (DRAs) appointed to oversee the program across the DC network.

Thresholds are established and monitored for each customer within SAP. They are determined by analyzing a customer's controlled substance purchase history and are authorized and assigned at on boarding. Orders that attempt to exceed a threshold are flagged and omitted from a shipment in SAP. DC management contacts customers to obtain reasons for threshold incursions, inquire about any business changes, and document the results. Customers may request a re-evaluation or increase to their existing controlled substance thresholds due to business requirements and/or an emergency situation. All threshold change requests must be documented, reviewed and approved by the appropriate DRA. Finally, ad hoc analytics are performed by each DRA for each market and customer base to support the CSMP.

Scope and Objectives

Internal Audit conducted an audit of the CSMP to assess the adequacy of, and compliance with, policies and procedures. The scope was limited to the US Pharma DC operations, including shipments by US Pharma to McKesson Medical-Surgical (MMS) customers. The audit period covered April 1, 2012 through September 15, 2012 and included the DCs located in Santa Fe Springs, CA; Delran, NJ; and Lakeland, FL.

Our objectives include, but are not limited to:

- Evaluate the effectiveness of the processes related to on-boarding new customers and assigning controlled substance thresholds;
- Validate that adequate controls have been implemented to monitor established thresholds and make modifications, as needed;
- Assess that procedures to identify, monitor, and report controlled substance orders to the DEA are adequate; and
- Validate that clear guidelines exist to determine and enforce the retention period for CSMP documentation.

Overall Conclusion

Green – Satisfactory

Based on the testing performed to meet our audit objectives, we conclude that controls to on-board new customers, assign and monitor thresholds, and report suspicious orders to the DEA are effective. However, the application of policies and procedures across the BUs and customer segments could be improved. Improvement was realized overall in the FY13 Internal Audit as compared to FY09 issues identified.

Issues have been communicated to the appropriate level of management and action plans have been obtained to address the risks noted.

Key Issues

Policies and procedures to document threshold reasoning and customer correspondence are not consistently followed for Retail National Accounts (RNA)/Chain Stores and institutional provider customer segments. RNA/chain and institutional provider segments represent two of three customer segments for US Pharma. Although thresholds are established for RNA customers and follow-up is performed when thresholds are met, customer questionnaires are not consistently completed at on-boarding, and threshold incursions are not documented. The McKesson sales representatives for RNA/chain and institutional providers are responsible to perform all customer communication and follow-up.

The Controlled Substance Monitoring Program (CSMP) policy requires the sales representative to complete a customer questionnaire during the on-boarding process. Additionally, outreach to each customer is required when a controlled substance order is omitted.

Management Action Plan

Management will ensure that a questionnaire is completed for all customer types as indicated in the CSMP policy.

Management will ensure that customer correspondence, noting the reason for a threshold incursion, is completed for all customer types as indicated in the CSMP policy.

Management will work with the Regulatory Affairs group to revise the questionnaire(s) and the CSMP policy (if deemed necessary) so that the documents are better tailored to RNA/chain and institutional providers.

Audit Committee Summary

US Pharma implemented enhancements to the Controlled Substance Monitoring Program (CSMP) in June 2008 to detect and prevent diversion of controlled substances. The CSMP includes policies and procedures, automated controls and Directors of Regulatory Affairs (DRAs) appointed to oversee the program across the DC network.

Controls to on-board new customers, assign and monitor thresholds, and report suspicious orders to the DEA are effective. However, the application of policies and procedures across the BUs and customer segments could be improved.

Issues have been communicated to the appropriate level of management and action plans have been obtained to address the risks noted.

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
1	**Retail National Accounts (RNA) and Institutional Providers** Although thresholds are established for RNA customers, documentation of customer questionnaires could not be provided for RNA/chain and institutional providers (such as hospitals and health systems). Outreach to each customer is required when a controlled substance order is omitted; this is known as a Level 1 review. Level 1 reviews were not documented for RNA/chain and institutional providers when controlled substance orders were omitted due to a threshold being met. The Controlled Substance Monitoring Program (CSMP) policy requires the sales representative to complete a customer questionnaire during the on-boarding process. A Level 1 review is required for every controlled substance order omitted.	Significance: Moderate Risk: Failure to evaluate new customers and complete supporting documentation may result in non-compliance with the CSMP program. Failure to contact customers to understand any changes to their business and/or controlled substance purchase volumes may result in non-compliance with the CSMP program.	Management will ensure that a questionnaire is completed for all customer types as indicated in the CSMP policy. Management will ensure that Level 1 reviews are completed for all customer types as indicated in the CSMP policy. Management will work with the Regulatory Affairs group to revise the questionnaire(s) and the CSMP policy (if deemed necessary) so that the documents are better tailored to RNA/chain and institutional providers.	Dave Gustin / Elaine Thomet	03/15/2013
2	**McKesson Medical-Surgical (MMS) Customers** Controls could be improved by further developing policies and procedures for the MMS business unit to address customer contact and questionnaires. • Level 1 reviews are not required and therefore were not documented for MMS customers. • Although questionnaires for MMS customers are retained, they are not required to be retained at the Pharma DC that services those customers.	Significance: Moderate Risk: The likelihood that the CSMP is applied consistently across BUs is decreased, which could result in non-compliance with CSMP program.	The current MMS process for on-boarding customers is documented via a required controlled substances questionnaire. Customer follow up (including but not limited to significant conversations regarding the customer's controlled substances purchases, policies & procedures, site visits) will be documented via a standard form. All documentation will be retained in accordance with the Records Retention Schedule. This on-boarding process will be documented in MMS' Controlled Substances Monitoring Program SOP. Questionnaires will be made available to McKesson Pharma distribution centers and Directors of Regulatory Affairs via a shared access drive. This will be documented in MMS' Controlled Substances Monitoring Program SOP. A formal written Controlled Substances Monitoring Program SOP is currently in	Alex Nagy Alex Nagy Alex Nagy	3/31/2013 6/30/2013 3/31/2013

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
			development.		
3	**Level 1 Reviews** Level 1 reviews on threshold incursions are not consistently completed and documented at the DCs and in compliance with the CSMP policy. Santa Fe Springs: Level 1 reviews were not completed for 9 of 20 controlled substance orders selected. Delran Level 1 reviews were not completed for 2 of 21 controlled substance orders selected. The remaining 19 samples included evidence of Level 1 review. However, the documentation did not detail the conversation with the customer describing the reason for the threshold incursion and any business changes that contributed to the increase in controlled substance purchases. Additionally, the date of the Level 1 review was not recorded. Lakeland: Level 1 reviews were not completed for 7 of 16 controlled substance orders selected.	Significance: Moderate Risk: Failure to contact customers to understand any changes to their business and/or controlled substance purchase volumes may result in non-compliance with the CSMP program.	Management will revise the CSMP policy to include additional guidance on performing Level 1 reviews. Annual training will be delivered to the sales representatives and individuals performing CSMP related tasks to ensure that the policy is interpreted and implemented accurately and consistently across the DC network.	Tracy Jonas	01/31/2013
4	**Access to Modify Thresholds in SAP** During a review of SAP access to modify controlled substance thresholds, it was noted that 17 of 26 individuals with access did not require access based on their job responsibilities. Only DRAs should require access to modify controlled substance thresholds in SAP.	Significance: Moderate Risk: Unauthorized changes to controlled substance thresholds can result in inappropriate purchases by the customer and non-compliance with McKesson policy.	Management will ensure that inappropriate access identified during this review is immediately corrected. Management will ensure that only SVP, Distribution Operations or Business Systems Director is authorized to grant access to modify controlled substance thresholds in SAP. Additionally, management will develop a process to periodically review the access to modify controlled substance thresholds in SAP for appropriateness and accuracy.	Keith McIntyre	01/31/2013

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
5	**Threshold Change Requests Self-Audit** Monthly self-audits of Threshold Change Requests (TCRs) were not performed. Between the third and eighth workday of every new month, DC management is required to validate the existence of a TCR for every adjustment made the previous month. Santa Fe Springs: Monthly self-audits of TCRs were not performed for any of three months selected (May 2012, June 2012, and August 2012). Delran: Monthly self-audits of TCRs were not performed between the third and eighth workday of every new month for any of three months selected. When a TCR did not exist, follow-up was not completed and documented. Lakeland: Monthly self-audits of TCRs were not performed for any of three months selected. However, the DC began performing monthly TCR self-audits as of September 2012.	Significance: Moderate Risk: Inappropriate changes to controlled substance thresholds can result in inappropriate purchases by the customer and non-compliance with McKesson policy.	Management will automate monthly reports from SAP so that the DCs can access the TCR reports to complete the self-audit timely. The Distribution Center Manager (DCM) will perform and document a second-level review of the monthly self-audit to confirm that appropriate follow-up was conducted in cases where a TCR did not exist. Annual training will be delivered to the sales representatives and individuals performing CSMP related tasks to ensure that the policy is interpreted and implemented accurately and consistently across the DC network.	Tracy Jonas	01/31/2013
6	**Customer Questionnaires** During a review of the completed customer questionnaires at the Lakeland DC, it was noted that 5 of 17 questionnaires selected were not signed by the sales representative. The sales representative is required to complete a customer questionnaire during the on-boarding process. Upon completion of the questionnaire, signatures are obtained from the customer and the sales representative to attest that all the information within is accurate and complete.	Significance: Low Risk: Failure to follow procedures for customer on-boarding documentation can result in non-compliance with McKesson policy.	Management will ensure that the sales representative signature has been obtained prior to approving the questionnaire and accepting the customer. Annual training will be delivered to the sales representatives and individuals performing CSMP related tasks to ensure that the policy is interpreted and implemented accurately and consistently across the DC network.	Tracy Jonas	01/31/2013

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
7	**Level 1 Review Self-Audit** Monthly self-audits of Level 1 reviews were not performed. Between the third and eighth workday of every new month, DC management is required to validate that a Level 1 review has been performed for each customer that was omitted due to CSMP thresholding the previous month. Santa Fe Springs: Monthly self-audits to validate the completion of Level 1 reviews were not performed for any of three months selected (May 2012, June 2012, and August 2012). Delran: Monthly self-audits to validate the completion of Level 1 reviews were not performed between the third and eighth workday of every new month for any of three months selected.	Significance: Low Risk: Failure to contact customers to understand any changes to their business and/or controlled substance purchase volumes may result in non-compliance with the CSMP program.	Management will automate the Level 1 monthly reports so that the DCs can access these reports to complete the self-audit timely. The DCM will perform and document a second-level review of the monthly self-audit to confirm that appropriate follow-up was conducted in cases where a Level 1 review was not completed. Annual training will be delivered to the sales representatives and individuals performing CSMP related tasks to ensure that the policy is interpreted and implemented accurately and consistently across the DC network.	Tracy Jonas	01/31/2013
8	**Threshold Change Requests** During a review of the TCRs at the Delran DC, it was noted that TCR documentation did not exist for 2 of 15 TCRs selected. Additionally, 2 of 15 TCRs that were approved for a temporary increase per SharePoint were incorrectly loaded as permanent threshold increases in SAP. All requests for a threshold change must be documented on the "Threshold Change Request" form located on SharePoint.	Significance: Low Risk: Inappropriate changes to controlled substance thresholds can result in inappropriate purchases by the customer and non-compliance with McKesson policy.	The DRA will ensure that a TCR is completed and approved in SharePoint before making any threshold changes in SAP. The DRA will ensure that the appropriate level of detail per the CSMP policy is included in the text field when adjusting a threshold in SAP.	Tracy Jonas	01/31/2013
9	**Document Retention Policy** The CSMP policy does not provide specific guidelines on the retention period for CSMP documentation. Per the DRAs, the DCs have retained all CSMP related hard copy documentation obtained prior to the SharePoint roll-out in 2010. After 2010, all documentation has been retained on SharePoint electronically.	Significance: Low Risk: CSMP documentation is not appropriately retained or disposed of.	Management will provide specific guidelines on the retention period for CSMP documentation.	Tracy Jonas	02/15/2013